

DHRD Course Announcement

DATE: September 1, 2011

FROM: John Shafer
Director, Division of Human Resource Development (HFC-60)

SUBJECT: COURSE ANNOUNCEMENT:
Blood Banking and Plasmapheresis I (BI201)

Rockville, MD

Begin: Monday, November 14 at 8:00 AM

End: Thursday, November 17 at 4:00PM

AUTHORIZED TRAVEL DATES:

Arrival: Sunday, November 13

Departure: Friday, November 18 (or schedule return flights **after 6:30 PM** Thursday)

Everyone is expected to return on the departure date unless there are extenuating circumstances ([See Accounting & Admin Info](http://homewoodsuites.hilton.com/en/hw/groups/personalized/R/RVCHMHW-BBF-20111113/index.jhtml?WT.mc_id=POG)) http://homewoodsuites.hilton.com/en/hw/groups/personalized/R/RVCHMHW-BBF-20111113/index.jhtml?WT.mc_id=POG.

POINTS OF CONTACT:

Participants seeking information or assistance with this training course should contact in the following order:

- 1) Immediate supervisor (first source of information and assistance)
- 2) New Hire Training Coordinators (for "new hire" related questions)
- 3) District Administrative Officer (AO) (Gov Trip, travel, and accounting code information)
- 4) Regional Training Officer (RTO) (cancellation, substitutions, hotel issues, pre-requisite waivers, and special requests for additional overnight stay)
- 5) Courtney Gilbert, Training Officer (final POC if the RTO is unavailable)

FDA/Division of Human Resource Development

850-942-8325 ext 106 Fax 850-942-8326

e-mail: Courtney.Gilbert@FDA.HHS.GOV

COURSE DESCRIPTION / OBJECTIVES:

Blood Banking and Plasmapheresis I (BI201)

This four day basic course is designed to provide an overview of the blood banking and source plasma program area. It will provide practical training on the methods and techniques used in conducting blood bank, source plasma and donor testing laboratory inspections. The course will consist of pre- course reading assignments, lectures and in-class exercises.

Objectives: Upon completion, participants will be able to:

1. Apply the appropriate compliance programs, policies, and regulations to conduct efficient inspections of blood and source plasma establishments.
2. Construct an accurate and meaningful FDA-483 using Turbo EIR as appropriate.
3. Identify the different types of blood establishments.
4. Identify the basic operations of blood and source plasma establishments and interpret the associated terminology.

Target Audience: This course is designed for Consumer Safety Officers, Compliance Officers and Supervisory Consumer Safety Officers who will be conducting, participating or reviewing inspections involving blood banks, source plasma centers and donor testing laboratories.

Continuing Education Units (CEUs): 2.8

PREREQUISITES:

Prior to attending the Blood Banking and Plasmapheresis I course, nominees must have:

1. Completed their New Hire training curriculum (FDA: Level I, including the audit) or completed the 6 month district training program (includes 3 week new hire program) if hired prior to Jan 1, 2002 and not Level I. State employees should have completed their new hire program and have experience working in the program area.
2. An active TURBO EIR account and have written a 483 in TURBO

3. Completed required pre-course reading

PRE-COURSE READING

1. Basic Blood Banking Immunology attachments:



Intro to Blood Banking.pdf Immunology.pdf Factors.pdf Tests using Immunoassays.pdf Answers to questions.pdf

2. Blood Banking Process & Genes & Blood Type:

- Blood Banking Process: <http://library.med.utah.edu/WebPath/TUTORIAL/BLDBANK/BLDBANK.html>
- Genes and Blood Type: <http://learn.genetics.utah.edu/units/basics/blood/types.cfm>

3. Regulations:

- 21CFR 211 http://www.access.gpo.gov/nara/cfr/waisidx_08/21cfr211_08.html
- 21 CFR 600 [Biological products: general](#) – Biological Products

4. Compliance Programs:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/CompliancePrograms/default.htm>

- CP 7342.001 - Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors
- CP 7342.002 - Inspection of Source Plasma Establishments, Brokers, Testing Laboratories, and Contractors
- CP 7342.008 - Inspection of Licensed Viral Marker Test Kits

COURSE COMPLETION REQUIREMENTS:

To successfully complete this course and receive a course certificate with CEUs*, each participant will be required to:

1. Complete pre-course reading assignment. Each course participant is required to read and study all the documents on the Pre-Course Reading list prior to attending the course. Course material will be presented based on a basic understanding of the concepts outlined in the reading materials.
2. Be on time and attend the entire course
3. Successfully complete and participate in all course assignments and activities. Each participant will be evaluated individually for each assignment/exercise.

Course Assessments/Exam Policy*

As an authorized provider of Continuing Education Units accredited through the International Association for Continuing Education and Training (IACET), DHRD courses are required to have an assessment(s) component (knowledge & application) to evaluate the effectiveness of the training presented and the participant's grasp of the material covered. Participants will receive only a pass/fail score. Minimum passing score is 70%.

SLOT ALLOCATIONS:

Regional Training Officers (RTOs) will allocate slots to the Districts utilizing the ORA survey data. Listed below are the districts and the number of slots allocated for each:

NER- 4
CER- 12
SER- 9
SWR-6
PAR- 5
States*- 3

International - 1
CBER-2
CDER-1
CDRH-1
CVM-1

***NOTE:** At Least 10% of the slots are reserved for state participants. Please refer all state inquiries to:

FDA/ORA Regional Training Officer (RTO)

Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts can not assign slots for these courses to a specific state without the approval of the Training Officer and concurrence of the RTO and/or DFRS (Mei –Ying Li). Funding for state employees to attend this course is to be provided by their state agency

DEADLINES / SPECIAL NOTICES:

Regional Training Officers, IA/International, and Center Training Contacts:

1. Please provide a copy of this announcement to each participant as soon as they are identified
2. **By COB Tuesday, September 27, 2011**, forward all participant names and registration information (see Attachment A) via e-mail to Courtney Gilbert.

Course Participants:

1. **Hotel Reservations must be made by COB Tuesday, October 4, 2011.** Participants and instructors who will be in travel status must confirm their reservation at the Hilton Garden Inn & Homewood Suites (240) 507-1900 room block: **“Blood Banking”** (See [LODGING INFORMATION](http://homewoodsuites.hilton.com/en/hw/groups/personalized/R/RVCHMHW-BBF-20111113/index.jhtml?WT.mc_id=POG) below for additional information.)
http://homewoodsuites.hilton.com/en/hw/groups/personalized/R/RVCHMHW-BBF-20111113/index.jhtml?WT.mc_id=POG
2. **By COB Tuesday, September 27, 2011**, complete the Attachment “A” send it via e-mail, **as a Word attachment** (Word Doc) to:
 - **FDA:** Your Regional Training Officer (RTO)
 - **FDA/Centers:** Your Center Training Contact.
 - **State:** FDA/ORA Regional Training Officer (RTO)
Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts can not assign slots for these courses to a specific state without the approval of the training Officer and concurrence of the RTO and/or DFRS (Mei –Ying Li). Funding for state employees to attend this course is to be provided by their state agency.

International: FDA/ORA/IA Lisa Romano at Lisa.Romano@fda.hhs.gov for approval

TRANSPORTATION:

- Travelers must select an airport and flight that is most cost effective to the Government, in accordance with the Federal Travel Regulations.
 - Reagan Washington National (DCA)
 - Baltimore Washington International (BWI)
 - Dulles International Airport (IAD)
- Rental cars are **NOT authorized**.
- DC Metro: <http://www.wmata.com/rail/>
- Shuttles (need 24 hours notice):
 - Maryland Service (301) 230-0000 <http://www.marylandshuttle.com/>
 - Blue Van (800) 258-3826

LODGING INFORMATION:

Hilton Garden Inn & Homewood Suites

14975 Shady Grove Road
Rockville, MD 20850
T: 240.507.1900
F: 240.314.7120

Lodging: \$183.00 tax **M&IE:** \$77

Reservations By: Tuesday, October 4, 2011

Check-in time: 3PM Checkout: 12PM

Room Block: Blood Banking

http://homewoodsuites.hilton.com/en/hw/groups/personalized/R/RVCHMHW-BBF-20111113/index.jhtml?WT.mc_id=POG

Hotel Cancellation Policy: No later than 24 hours prior to your intended arrival date to avoid cancellation charges. If you cancel, please obtain a cancellation number from the hotel.

COURSE LOCATION:

Hilton Garden Inn & Homewood Suites
14975 Shady Grove Road
Rockville, MD 20850
Conference room lower level

Metro: The hotel is located off the Red Line at the Shady Grove stop. Contact the hotel for complimentary shuttle service to/from the metro/hotel.

Parking at hotel is complimentary.

ACCOUNTING AND ADMINISTRATIVE INFORMATION

- When a participant fails to confirm a hotel reservation by the deadline and cannot obtain lodging at the negotiated rate, any additional cost must be paid by the nominee's district, unless the district obtains prior approval from DHRD. Approval requests should be forwarded to the Training Officer for a case by case review by DHRD management.
- Employees should stay at the designated hotel with the negotiated room block. If the employee chooses to stay at a different hotel, the employee would be responsible for any costs incurred above and beyond what the expenses would have been if the employee stayed at the hotel with the negotiated room block. Reimbursements will be made at the negotiated rate. If the employee does not use the room block; the employee must use Gov Trip to book the hotel.
- When accounting codes are released approximately 4 weeks prior to the course, the Training Officer will send a Travel Authorization Memo to ORA participants and FDA instructors. Tax exempt forms can be found at (*OPM web link when forms are accepted in the state*)
- Rental cars are not authorized
- Civilian dress is business casual as defined by your district.
- Commissioned Corps Officers are required to be in uniform while attending training.
- Temperature may vary in the conference room – please bring layers of appropriate clothing.
- **Please note:** Due to budget constraints, DHRD will no longer pay for UPS return shipment of student manuals, etc.
- **Request & justification to stay an additional night (if applicable): The participant's supervisor must submit requests in advance via email to your RTO.** . One request can be provided for all students listed from the same District/Lab. Approval must be granted **prior** to the student traveling to the course. DHRD is unable to assist in reimbursement for "after the fact" requests. The RTO will forward requests to the DHRD Training Officer for review/approval.

The request for staying an additional day must include:

1. The factors addressing the reason/justification for the request such as:
 - District policy indicating what is an "unreasonable hour" for travel (if citing undue hardship to the employee)
 - Available flight times (contract and non-contract)
 - Airports researched (if more than one in the area)
 - Any related cost comparison (non-contract fare vs. staying the extra night)
2. Statement of supervisory concurrence

If approved, your voucher needs to include a copy of the e-mail granting approval to stay the extra night

- After the course, FDA participants should report their actual course time in the "Miscellaneous Operations Accomplishment Hours" screen in FACTS following all applicable guidance. The data entered should include the appropriate Operation Code 84 for participants and 83 for instructors, PAC 42R800.

SPECIAL NEEDS:

FDA provides reasonable accommodations to employees with disabilities. If you need a reasonable accommodation for any part of the training process - due to medical conditions, physical limitations or particular learning challenges - please notify the Training Officer prior to the course. Reasonable accommodations will be

granted on a case-by-case basis. For Voice TTY or other interpreting needs, please contact Interpreting Services at the following e-mail address: interpreting.services@oc.fda.gov.

/s/

John Shafer
Director, DHRD

Attachment for Participant Registration Information

Please submit the information as listed in the format and order below as a Word attachment (Word Doc) no later than **COB Tuesday, September 27, 2011** via e-mail to:

FDA/ORA: your Regional Training Officer (RTO).

FDA/Centers: Your Center Training Contact.

FDA/ORA Regional Training Officer (RTO)

Regional and/or District Offices will refer any states contacting them about this training course to the Regional Training Officer. Regions and Districts can not assign slots for these courses to a specific state without the approval of the training Officer and concurrence of the RTO and/or DFSR (Mei –Ying Li). Funding for state employees to attend this course is to be provided by their state agency

List State/Local Agency: _____

International: FDA/IA Lisa Romano at Lisa.Romano@fda.hhs.gov for approval

List Country and Agency: _____

Blood Banking and Plasmapheresis I (BI201)
Rockville, MD
November 14-17, 2011

Participant Registration Information
Participant's Legal Name:
Position/Title:
GS Series and Grade:
Agency/Organization/Division:
Duty Station (Complete Address with Mail Code):
Business Phone Number and Extension:
Fax Number:
E-mail address:
Supervisor's Name:
Supervisor's Phone Number:
Arrangements needed to accommodate special needs (if any):
Name and Phone Number to contact in case of emergency (optional):
Course Prerequisites:
1. Completion date of your new hire training curriculum FDA: Level I (including the audit) or 6 month district training program if hired prior to Jan 1, 2002 and not Level I _____ State: state employees should have completed their new hire training program _____
2. Have an active TURBO EIR account and have written a 483 in TURBO _____
3. Complete pre-course reading